

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Previously presented) A purified rifaximin α , a polymorph of the antibiotic rifaximin, wherein said rifaximin α has a water content of 3% or less, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°.
2. (Original) The rifaximin α according to claim 1, wherein said water content is between 2.0% and 3.0%.
3. (Original) A purified rifaximin β , a polymorph of the antibiotic rifaximin wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°, 14.4°; 17.1°; 17.9°; 18.3°; 20.9°.
4. (Original) The rifaximin β according to claim 3, wherein said water content is between 5.0% and 6.0%.
5. (Original) A purified rifaximin γ , a polymorph of the antibiotic rifaximin wherein said rifaximin γ has a water content between 1.0% and 2.0% and

produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0° ; 7.1° ; 8.4° .

6. (Currently amended) A process for the production of rifaximins α , β and γ , comprising:

reacting a molar equivalent of rifamycin O with an excess of 2-amino-4-methylpyridine in a solvent mixture of water and ethyl alcohol in a volumetric ratio between 1:1 and 2:1, for a period of time between 2 and 8 hours, at a temperature between 40°C and 60°C ,

treating the reaction mass at room temperature with a solution of ascorbic acid in a mixture of water, ethyl alcohol and concentrated aqueous hydrochloric acid,

adjusting the pH of the reaction mass to pH 2.0 with a concentrated aqueous solution of hydrochloric acid,

filtering the suspension,

washing any resulting solid with the water/ethyl alcohol solvent mixture to obtain raw rifaximin,

purifying the raw rifaximin by dissolving it in ethyl alcohol at a temperature between 45°C and 65°C ,

precipitating the raw rifaximin by adding water and by lowering the temperature of the suspension to between 0°C to 50°C under stirring for a period of time between 4 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying it under vacuum or under conditions of normal pressure, with or without a drying agent, at a temperature between room temperature and 105°C, for a period of time between 2 and 72 hours to the water content required to form rifaximin α , β or γ .

7. (Original) The process according to claim 6, wherein said 2-amino-4-methylpyridine is from 2.0 to 3.5 molar equivalents.

8. (Original) The process according to claim 6, wherein said water added to precipitate the raw rifaximin is in a weight amount between 15% and 70% with respect to the weight amount of ethyl alcohol used for the dissolution.

9. (Original) The process according to claim 6 for the production of rifaximin α , wherein after the addition of water to the raw rifaximin, the temperature is lowered to a value between 28°C and 32°C in order to cause the beginning of the crystallization,

stirring the resulting suspension at a temperature between 40°C and 50°C for a period of time between 6 and 24 hours,

cooling the suspension to 0°C for a period of time between 15 minutes and one hour,

filtering the suspension, washing the resulting solid with water, and

drying the washed solid until a water content lower than 4.5% is reached.

10. (Original) The process according to claim 9, wherein said water content is between 2.0% and 3.0%.

11. (Original) The process according to claim 6 for the production of rifaximin β ,

wherein after the addition of water to the raw rifaximin, the temperature is lowered to a value between 28°C and 32°C in order to cause the beginning of the crystallization,

stirring the resulting suspension at a temperature between 40°C and 50°C for a period of time between 6 and 24 hours,

cooling the suspension to 0°C for a period of time between 15 minutes and one hour,

filtering the suspension, washing the resulting solid with water, and

drying the washed solid until a water content higher than 4.5% is reached.

12. (Original) The process according to claim 11, wherein said water content is between 5.0% and 6.0%.

13. (Original) The process according to claim 6 for the production of rifaximin γ , wherein after the addition of water to the raw rifaximin, the temperature is lowered to a value between 28°C and 32°C in order to cause the beginning of the crystallization,

cooling the suspension to 0°C for a period of time between 6 and 24 hours,

filtering the suspension, washing the resulting solid with water and
drying the washed solid until a water content between 1.0% and 2.0% is reached.

14. (Original) A process for the production of rifaximin α , comprising
suspending rifaximin γ in a solvent mixture of ethyl alcohol/water in a volumetric
ratio of 7:3,

heating the suspension at a temperature between 38°C and 50°C, under
stirring, for a period of time between 6 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying the washed solid until a water content lower than 4.5% is reached.

15. (Original) The process according to claim 14, wherein said water content
is between 2.0% and 3.0%.

16. (Original) A process for the production of rifaximin β , comprising
suspending rifaximin γ in a solvent mixture of ethyl alcohol/water in a
volumetric ratio of 7:3,

heating the suspension at a temperature between 38°C and 50°C, under
stirring, for a period of time between 6 and 36 hours,

filtering the suspension,

washing the resulting solid with water, and

drying the washed solid until a water content higher than 4.5% is reached.

17. (Original) The process according to claim 16, wherein said water content is between 5.0% and 6.0%.

18. (Original) A process for the production of rifaximin γ , comprising
dissolving rifaximin α or β in ethyl alcohol at a temperature between 50°C and 60°C,

adding demineralized water until an ethyl alcohol/water volumetric ratio equal to 7:3 is reached,

cooling the solution to 30°C under strong stirring,

further cooling the resulting suspension to 0°C for a period of time between 6 and 24 hours,

filtering said suspension,

washing the resulting solid with water, and

drying the solid until a water content lower than 2.0% is reached.

19. (Original) A process for the production of rifaximin β , comprising keeping rifaximin α in an ambient environment having a relative humidity higher than 50% for a period of time between 12 and 48 hours until said rifaximin α is converted into rifaximin β .

20. (Original) A process for the production of rifaximin α , comprising drying rifaximin β under atmospheric pressure, or under vacuum, or in the presence of a drying agent, at a temperature between the room temperature and 105°C, for a period of time between 2 and 72 hours until said rifaximin β is converted into rifaximin α .

21. (Currently amended) A composition comprising a predetermined specified amount of rifaximin α , rifaximin β or rifaximin γ in combination with excipients suitable for oral administration, wherein said rifaximin α has a water content of 3% or less, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°, wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°; 14.4°; 17.1°; 17.9°; 18.3°; 20.9°, and wherein said rifaximin γ has a water content between 1.0% and 2.0% and produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0°; 7.1°; 8.4°.

22. (Original) The composition according to claim 21, wherein said

excipients are suitable for the production of coated and uncoated tablets, hard and soft gelatin capsules, sugar-coated pills, lozenges, wafer sheets, pellets and/or powders.

23. (Currently amended) A composition comprising a ~~predetermined~~ specified amount of rifaximin α , rifaximin β or rifaximin γ in combination with excipients suitable for topical administration, wherein said rifaximin α has a water content of 3% or less, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°; wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°; 14.4°; 17.1°; 17.9°; 18.3°; 20.9°, and wherein said rifaximin γ has a water content between 1.0% and 2.0% and produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0°; 7.1°; 8.4°.

24. (Original) The composition according to claim 23, wherein said excipients are suitable for the production of ointments, pomades, creams, gels and lotions.

25. (Currently amended) A composition comprising ~~predetermined~~ specified amounts of rifaximin α , rifaximin β , or rifaximin γ or any combination thereof, in combination with pharmaceutically acceptable excipients, wherein said rifaximin α has a water content of 3% or less, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°, wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°; 14.4°; 17.1°; 17.9°; 18.3°; 20.9°, and wherein said rifaximin γ has a water content between 1.0% and 2.0% and produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0°; 7.1°; 8.4°.

26. (Original) A method for treating a patient in need of antibiotic therapy, comprising administering the composition according to claim 25 to said patient.

27. (Original) The method according to claim 26, wherein said composition is administered orally.

28. (Original) The method according to claim 26, wherein said composition is administered topically.

29. (Currently amended) A pharmaceutical composition comprising the rifaximin α according to claim 1 in combination with pharmaceutically acceptable excipients.

30. (Currently amended) A pharmaceutical composition comprising the rifaximin β according to claim 3 in combination with pharmaceutically acceptable excipients.

31. (Currently amended) A pharmaceutical composition comprising the rifaximin γ according to claim 5 in combination with pharmaceutically acceptable excipients.

32. (Previously presented) The composition according to claim 23, wherein the predetermined amount of rifaximin α is 100%.

33. (New) A pharmaceutical composition prepared by combining purified rifaximin α , purified rifaximin β , or purified rifaximin γ or any combination thereof, with a pharmaceutically acceptable excipient, wherein said rifaximin α has a water content of 3% or less, and produces a powder X-ray diffractogram showing peaks at values of the diffraction angles 2θ of 6.6°; 7.4°; 7.9°; 8.8°; 10.5°; 11.1°; 11.8°; 12.9°; 17.6°; 18.5°; 19.7°; 21.0°; 21.4°; 22.1°, wherein said rifaximin β has a water content higher than 4.5% and produces a powder X-ray

diffractogram showing peaks at values of the diffraction angles 2θ of 5.4°; 6.4°; 7.0°; 7.8°; 9.0°; 10.4°; 13.1°, 14.4°; 17.1°; 17.9°; 18.3°; 20.9°, and wherein said rifaximin γ has a water content between 1.0% and 2.0% and produces a powder X-ray diffractogram showing a mainly amorphous profile and few significant peaks at values of diffraction angles 2θ of 5.0°; 7.1°; 8.4°.

34. (New) The composition according to claim 33, wherein said pharmaceutically acceptable excipients are suitable for oral administration.

35. (New) The composition according to claim 34, wherein said excipient is suitable for the production of coated and uncoated tablets, hard and soft gelatin capsules, sugar-coated pills, lozenges, wafer sheets, pellets and/or powders.

36. (New) The composition according to claim 33, wherein said pharmaceutically acceptable excipient is suitable for topical administration.

37. (New) The composition according to claim 36, wherein said pharmaceutically acceptable excipient is suitable for the production of ointments, pomades, creams, gels and lotions.